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Proposed Maximum Residue Limit

PMRL2014-66

# Mesotrione

*(publié aussi en français)*

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on MGI-tolerant soybeans to the product label of Callisto 480SC, containing technical grade mesotrione, is acceptable. The specific uses approved in Canada are detailed on the label of Callisto 480SC, *Pest Control Products Act* Registration Number 27833.

The evaluation of this mesotrione application indicated that the end-use product has merit and value and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for mesotrione is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Standards Council of Canada.

The proposed MRLs, to replace or be added to the MRLs already established for mesotrione, are as follows.

**Table 1 Proposed Maximum Residue Limits for Mesotrione**

Common Name	Residue Definition	MRL (ppm) <sup>1</sup>	Food Commodity
Mesotrione	2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione	0.05	Soybean flour
		0.03	Dry soybeans <sup>2</sup>

ppm = parts per million

<sup>2</sup> The MRL is proposed to replace the currently established MRL of 0.01 ppm for dry soybeans.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

## **International Situation and Trade Implications**

Mesotrione is concurrently being registered on MGI-tolerant soybeans in Canada and the United States. The MRLs proposed for mesotrione in Canada are the same as corresponding tolerances to be promulgated in the United States. Once established, the American tolerances for mesotrione will be listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there are no Codex MRLs<sup>1</sup> listed for mesotrione in or on any commodity on the Codex Alimentarius Pesticide Residues in Food webpage.

## **Next Steps**

The PMRA invites the public to submit written comments on the proposed MRLs for mesotrione up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

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<sup>1</sup> The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.



## Appendix I

### Summary of Field Trial Data Used to Support the Proposed MRLs

Residue data from field trials conducted in the United States, including Canadian representative growing regions, were submitted to support the domestic use of Callisto 480SC on MGI-tolerant soybeans. Mesotrione was applied to MGI-tolerant soybeans at exaggerated rates, and harvested according to label directions. In addition, a processing study in treated soybeans was reviewed to determine the potential for concentration of residues of mesotrione into processed commodities.

### Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for mesotrione was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs for soybean commodities.

**Table A1. Summary of Field Trial and Processing Data Used to Support Maximum Residue Limits (MRLs)**

Commodity	Application Method/ Total Application Rate (g a.i./ha)	Preharvest Interval (days)	Residues (ppm)		Experimental Processing Factor
			Min	Max	
MGI-tolerant soybean seed	Preplant incorporated or at planting (225 g a.i./ha) + postemergent ground spray (125 g a.i./ha)	43-106	<0.01	0.025	Soybean flour: 1.9×; No concentration observed in oil, meal, hulls

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of mesotrione. Residues of mesotrione in these crop commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.